

enVista®

one-piece hydrophobic acrylic intraocular lens

preloaded

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DEVICE DESCRIPTION

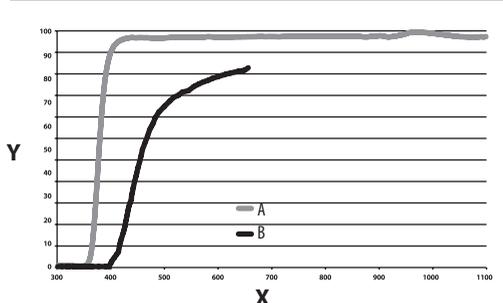
The enVista® one-piece hydrophobic acrylic intraocular lens (enVista IOL) was developed to replace the natural crystalline lens in adult patients in whom the cataractous lens has been removed.

The enVista IOL has an aspheric optic that is designed to be free of spherical aberration through the incorporation of a proprietary spherical aberration-neutral optic design that does not influence the pre-surgical corneal spherical aberration profile. The optic is designed with the SureEdge™, posterior squared step edge to provide a 360-degree PCO barrier. The enVista IOL employs an Accuset™ haptic with a broad, modified C-loop design and optic-haptic offset to facilitate improved contact and stability within the capsular bag. The enVista material that makes up the TruSight™ optic has been assessed for glistening-free capacity and scratch resistance. Incorporated StableFlex™ technology allows for enhanced lens compliance for ease of loading, premium control through lens delivery, and efficient optical recovery following implantation.

PHYSICAL CHARACTERISTICS OF enVista MODEL MX60PL

Lens / Haptic Material	Hydrophobic acrylic (hydroxyethyl methacrylate (HEMA)-polyethylene glycol phenyl ether acrylate (poly(EGPEA)-styrene copolymer, crosslinked with ethylene glycol dimethacrylate)
Material Characteristics	Index Of Refraction: 1.53 @ 35°C; Specific Gravity: 1.19 g/ml
Optic Type / Powers	Aspheric / 0.0 to +34.0 Diopters (0.0 to +10.0 in 1.0 Diopter increments, +10.0 to +30.0 in 0.5 Diopter increments, +30.0 to +34.0 in 0.5 Diopter increments)
Dimensions	Body Diameter: 6.0 mm; Overall Diameter: 12.5 mm; Haptic Angle: 0° See figure 1 with chart's X value = Wavelength (nm) and Y value = % Transmittance; chart compares the transmittance curve of an enVista Lens to a 53 Year Old Human Lens. A = +20 Diopter enVista Lens and B = 53 Year Old Human Lens. NOTE: Light transmittance values for an IOL material may vary slightly depending on the method of measurement. Reference: 53 year old human lens data from Boettner, E.A. and Wolter, J.R., "Transmission of the Ocular Media," Investigative Ophthalmology, 1:776-783, 1962
Spectral Transmittance	

1. Atramiņlementu kampas 0 laipsniņū



INDICATIONS

The enVista one-piece hydrophobic acrylic IOL (Model MX60PL) is indicated for primary implantation in the capsular bag of the eye in adult patients for visual correction of aphakia following removal of a cataractous lens for improved uncorrected distance vision.

WARNINGS

Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:

1. Recurrent severe anterior or posterior segment inflammation or uveitis.
2. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
3. Surgical difficulties at the time of cataract extraction, which might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
4. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
5. Circumstances that would result in damage to the endothelium during implantation.
6. Suspected microbial infection.
7. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.

PRECAUTIONS

1. Do not attempt to resterilize the lens as this can produce undesirable side effects.
2. Do not use if product sterility or quality is thought to be compromised due to damaged packaging or signs of leakage (such as the loss of saline storage solution, or the presence of salt crystallization).
3. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.
4. Do not store the lens at a temperature greater than 43°C (109°F) or lower than 0°C (32°F). Do not autoclave the intraocular lens.
5. Do not re-use the lens. It is intended for permanent implantation. If explanted, sterility and proper function cannot be assured.
6. The safety and effectiveness of the enVista IOL have not been substantiated in patients with pre-existing ocular conditions and intraoperative complications (see below). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions. Physicians considering lens implantation in such patients should explore the use of alternative methods of aphakic correction and consider lens implantation only if alternatives are deemed unsatisfactory in meeting the needs of the patient.

MEDICAL DEVICE RE-USE STATEMENT

If this product is reprocessed and/or re-used, Bausch + Lomb cannot guarantee the functionality, material structure, or cleanliness or sterility of the product. Re-use could lead to illness, infection and/or injury to the patient or user and, in extreme incidents, death. This product is labeled as 'single-use' which is defined as a device intended to be used once only for a single patient.

Before Surgery

- Retinal conditions or predisposition to retinal conditions, previous history of, or a predisposition to, retinal detachment or proliferative diabetic retinopathy, in which future treatment may be compromised by implanting this lens.
- Amblyopia
- Clinically severe corneal dystrophy (e.g., Fuchs')
- Rubella, congenital, traumatic or complicated cataracts
- Extremely shallow anterior chamber, not due to swollen cataract
- Recurrent anterior or posterior segment inflammation of unknown etiology, or any disease producing an inflammatory reaction in the eye (e.g. iritis or uveitis).
- Aniridia
- Iris neovascularization
- Glaucoma (uncontrolled or controlled with medication)
- Microphthalmos or macrophthalmos
- Optic nerve atrophy
- Previous corneal transplant
- Pre-existing ocular conditions which may negatively impact stability of the implant.

During Surgery

- Mechanical or surgical manipulation required to enlarge the pupil
 - Vitreous loss (significant)
 - Anterior chamber bleeding (significant)
 - Uncontrollable positive intraocular pressure
 - Complications in which the IOL stability could be compromised
7. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such problems. The physician must determine the benefits to be derived from lens implantation when such conditions exist.
 8. A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.
 9. Care should be taken to remove viscoelastic from the eye at the close of surgery.

ADVERSE EVENTS

The incidence of adverse events experienced during the clinical trial was comparable to or lower than the incidence reported in the historic control ("FDA grid") population. The enVista IOL demonstrated favorable safety compared with the Control IOL and the historical control (cf. ISO 11979-7 SPE) population, with no increase in incidence or severity of adverse events (AEs) compared with the Control IOL and no serious adverse events (SAEs) in the study eye. Overall, no safety signals were associated with the IOLs during this study. As with any surgical procedure, risk is involved. Potential adverse events accompanying cataract or implant surgery may include, but are not limited to, the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cystic membrane, iris prolapse, hypopyon, transient or persistent glaucoma, acute corneal decompensation, toxic anterior segment syndrome (TASS), and secondary surgical intervention. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration or iridectomy for pupillary block, wound leak repair, and retinal detachment repair.

CALCULATION OF LENS POWER

SUGGESTED A-CONSTANT: 119.1

(OPTICAL BIOMETRY)

The recommended A-Constant of 119.1 is intended for use with axial length measurements obtained by optical biometry. Use of axial length measurements by other techniques (e.g. Applanation A-scan) will normally require a different lens constant. This number is a guideline only and is based on an evaluation of clinical data obtained using the IOL Master. The physician should determine preoperatively the power of the lens to be implanted.

DIRECTIONS FOR USE

1. Prior to implanting, examine the lens package for type, power, and proper configuration.
2. Open the peel pouch and remove the vial in a sterile environment.
3. Remove the lid from the vial.
4. Remove the SnapSet™ IOL shuttle from the vial by grasping the tab on the top.
5. The SnapSet IOL shuttle may be flushed with sterile balanced salt solution during preparation for delivery.
6. The SnapSet IOL shuttle is designed for use with the enVista IOL (Model MX60PL) and the Bausch + Lomb SimpliflEYE™ preloaded delivery system. Refer to the Bausch + Lomb SimpliflEYE preloaded delivery system Directions for Use for additional information.
7. There are various surgical procedures that can be utilized, and the surgeon should select a procedure that is appropriate for the patient. Surgeons should verify that appropriate instrumentation is available prior to surgery.

OVERVIEW OF CLINICAL STUDIES

Clinical studies have been conducted on the enVista single-piece IOL (model MX60) and the parent exact X-60 three-piece IOL (model X-60). The results of clinical investigations provide reasonable assurance that the Model MX60 IOL is safe and effective for the visual correction of aphakia following cataract extraction.

For the enVista MX60 clinical study, all subjects in the safety analysis set were evaluated for IOL glistenings at Form 3 and Form 4 visits. IOL glistenings were evaluated via retroillumination slit lamp examination utilizing a photographic grading scale provided in the protocol. The grading scale consisted of (in order of severity), "none, grade 0 (trace), grade 1, 2, 3, or 4." No glistenings of any grade were reported for any subject at any visit in the clinical study.

9. LOW SUPPLIED Pakuotė sterilizuota gama spinduliais

The enVista IOL (Model MX60PL) is preloaded in the SnapSet IOL shuttle and individually packaged in a sterile vial (containing a 0.9% saline solution), within a peel pouch, and should only be opened under sterile conditions. A patient card and self-adhesive labels are supplied to provide traceability of the lens. **The package is sterilized by gamma irradiation.**

EXPIRATION DATE

Sterility is guaranteed unless the pouch is damaged or opened. The expiration date on the lens package is the sterility expiration date. This lens should not be implanted after the indicated sterility expiration date.

ADVERSE EVENT REPORTING

Adverse events and/or potentially sight threatening complications that may be regarded as lens related and that were not previously expected in nature, severity or degree of incidence should be reported within five (5) days to Bausch + Lomb Incorporated. This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation.

Physicians are encouraged to report these events in order to aid in identifying emerging or potential problems with intraocular lenses. These problems may be related to a specific lot of lenses or may be indicative of long-term effects associated with these lenses or with IOLs in general. If you wish to report a problem, please call Bausch + Lomb at 1-800-338-2020.

PATIENT REGISTRATION INSTRUCTIONS AND REPORTING REGISTRATION

Each patient who receives an enVista IOL must be registered with Bausch + Lomb at the time of lens implantation. Registration is accomplished by completing the Implant Registration Card that is enclosed in the lens package and mailing it to Bausch + Lomb. Patient registration is essential and will assist Bausch + Lomb in responding to adverse reaction reports and/or potentially sight-threatening complications. An implant identification card is supplied in the lens package and must be given to the patient.

RETURNED GOODS POLICY

All product being returned must be accompanied by a returned goods authorization number issued by Bausch + Lomb Customer Service. Call 1-800-338-2020 for return authorization and full policy information.

WARRANTY

Bausch + Lomb Incorporated warrants that the product, when delivered, will conform to all applicable laws and the manufacturer's then current version of the published specifications for such product in all material respects and will be free from defects in material and workmanship.

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SYMBOLS AND ABBREVIATIONS USED ON LABELING

Symbol or Abbreviation	Symbol or Abbreviation Title	Symbol or Abbreviation	Symbol or Abbreviation Title
PC	Posterior Chamber	Ø _B	Body Diameter (Optic Diameter)
UV	Ultraviolet	Ø _I	Overall Diameter (Overall Length)
D	Diopter		

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